

**CLARITIN- loratadine tablet, chewable**  
**Bayer HealthCare LLC.**

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**Children Claritin® Chewables Perrigo**

**Active ingredient (in each tablet)**

Loratadine 5 mg

**Purpose**

Antihistamine

**Uses**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

**Warnings**

**Do not use** if you have ever had an allergic reaction to this product or any of its ingredients.

**Ask a doctor before use if you have** liver or kidney disease. Your doctor should determine if you need a different dose.

**When using this product** do not take more than directed. Taking more than directed may cause drowsiness.

**Stop use and ask a doctor if** an allergic reaction to this product occurs. Seek medical help right away.

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

adults and children 6 years and over	chew 2 tablets daily; not more than 2 tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 tablet in 24 hours

children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

### **Other information**

- phenylketonurics: contains phenylalanine 1.4 mg per tablet
- safety sealed: do not use if the individual blister unit imprinted with Children's Claritin® is open or torn
- store between 20° to 25°C (68° to 77°F)

### **Inactive ingredients**

artificial grape flavor, aspartame, colloidal silicon dioxide, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

### **Questions or comments?**

**1-800-CLARITIN (1-800-252-7484) or [www.claritin.com](http://www.claritin.com)**

Dist by: Bayer HealthCare LLC, Whippany, NJ 07981

Product of Ireland

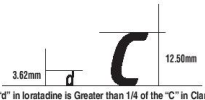
### **PRINCIPAL DISPLAY PANEL**

SIZE: 3.00 x 1.50 x 3.875  
MATERIAL: 0.014 SBS  
PRINTED SIDE UP

# 40 CT GRAPE CHEWABLE LORATADINE



**CODE AREA PANEL:**  
Areas MUST meet background color across entire code area (background color)  
Must use a color, preferably a darker one than the job. (PMS is not acceptable)  
No text or graphics within the code area.  
Print facing down (the top of the box is the bottom of the code area)  
• Background color must be darker than the code area  
• Background color must be darker than the code area



the "d" in Claritin is Greater than 1/4 of the "C" in Claritin



The Bayer Cross is Less than the "C" in Claritin  
Current Size: 7mm  
Current "C" Size: 12.50mm  
Cross Meets Ratio Requirements of 7mm (.275") or larger  
1/4th of Cross required Clear Space (7mm) = 1.75mm  
1/6th of PDP Shortest Side (76.2mm) = 12.7mm

## ARTWORK

**Client:** Bayer HealthCare/USA Consumer Healthcare  
**Project Type:** Production Art  
**Brand:** Claritin  
**Bayer/58rd/Logo:** CLARITIN CHILDREN Tablets 40 Piece (PCE) Claritin PCD0016768  
**Item#:** C00011389 **Die:** BY0894  
**EPC (EAN/UPC):** 041100575685 **UPC Specs:** M: 100% H: 10.576 mm  
**C128/12a/15/20Matrix/Pharma:** 24M498/C1 **Software:** Illustrator 2020  
**File Name:** C00011389\_CLARITIN\_Children\_Grape\_Tablet\_40ct\_Carton\_r2

**Job #:** 402383846 **Version:** r2  
**Date:** 14JUN2021  
**Printer:** WestRock Alligan  
**Printer Location:** MI, US

**All Images/Codes are FINAL**

**NOTE: THIS COLOR PROOF INDICATES COLOR BREAK ONLY AND MAY NOT ACCURATELY REFLECT ACTUAL PRODUCTION COLOR.**

### Printing Inks

1 Cyan	5 PMS 287
2 Magenta	6 PMS 3005
3 Yellow	Varnish
4 PMS 186	

### Non-Printing

<input type="checkbox"/> cornbo
<input type="checkbox"/> flexo
<input type="checkbox"/> offset
<input type="checkbox"/> screen
<input type="checkbox"/> pressure
<input type="checkbox"/> hot stamp
<input type="checkbox"/> digital
<input type="checkbox"/> dry offset

### DRUG FACTS (1/10) (Updated 05/2019)

CATEGORY	REQUIRED	ACTUAL IN FILE
Drug Facts Title	5 pt	5 pt
Drug Facts Continued	8 pt	8 pt
Warnings*	8 pt bold italic	8 pt
Side Effects	8 pt	8 pt
Body Text	8 pt	8 pt
Buttons	8 pt	8 pt
Headings	8 pt	8 pt
Box and Bar Lines	0.5 pt rule	0.5 pt
Character Per inch	No more than 30	30

\*Headings are not less than 8pt. Body text is not less than 6pt. Drug Facts Continued is not less than 8pt. 1/10th of the box is not less than 8pt.

CLARITIN

loratadine tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-0104	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LORATADINE (UNII: 7AJ03BO7QN) (LORATADINE - UNII: 7AJ03BO7QN)		LORATADINE	5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)				
ALUMINUM OXIDE (UNII: LMI26O6933)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MANNITOL (UNII: 3OWL53L36A)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
ASPARTAME (UNII: Z0H242BBR1)				
Product Characteristics				
Color	purple (Light purple tablet with slightly mottled appearance)	Score	no score	
Shape	ROUND	Size	10mm	
Flavor	GRAPE	Imprint Code	C	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-0104-1	1 in 1 CARTON	02/08/2023	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:11523-0104-2	2 in 1 CARTON	02/08/2023	
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:11523-0104-3	3 in 1 CARTON	02/08/2023	
3		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

4	NDC:11523-0104-4	4 in 1 CARTON	02/08/2023	
4		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:11523-0104-5	6 in 1 CARTON	02/08/2023	
5		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:11523-0104-6	8 in 1 CARTON	02/05/2023	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA210033	02/05/2023	

**Labeler** - Bayer HealthCare LLC. (112117283)

Revised: 12/2024

Bayer HealthCare LLC.